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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,914	07/25/2003	Anan Chuntharapai	50474/017002	2414

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
04/30/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/626,914	CHUNTHARAPAI ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10,11,14,23,25,28,31,37,38,46 and 49-56* is/are pending in the application.

4a) Of the above claim(s) *10,11,46,49,50 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,14,23,25,28,31,37,38,51,53-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/24/04 and 7/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of Group I in the reply filed on 1/03/07 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Regarding applicants comments about serious burden, the M.P.E.P. § 803 states that: "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the Examiner by the examination of groups.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 22 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/03/07. Said claims have been cancelled.

3. Applicant's election of antibody produced by hybridoma 7B6.15.11 in the reply filed on 1/03/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Applicant's election without traverse of humanized antibody and cytotoxic agent in the reply filed on 10/17/07 is acknowledged.

5. Claims 10,11,46,49,50,52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/03/07 and 10/17/07. The elected species of antibody (7B6.15.11) has the properties of the antibody of claim 23.

6. Claims 1-5,14,23,25,28,31,37,38,51,53-56 are under consideration.

7. The replacement drawing for Figure 5B were received on 1/28/08 and is approved.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-3,23,37,38,51,53,54,56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The instant claims encompass an agonist antibody which binds TACI receptor. The specification discloses an amino acid sequence encoding a single human TACI. It appears that a murine TACI was known in the art. The term TACI as defined in the specification includes a vast collection of unknown mutants and variants of murine or human TACI. Said term also encompasses TACI derived from any mammalian species. The identity of the aforementioned unknown TACI mutants, variants or alleles and mammalian TACIs(other than the aforementioned mouse or human TACI) is unpredictable. With the exception of the aforementioned mouse or human TACI of SEQ. ID. No 3, the skilled artisan cannot envision the detailed structure of the encompassed "agonist antibody which binds TACI receptor" and therefore conception is not achieved

until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. In addition claim 3 discloses BCMA receptor and claim 23 recites BLyS wherein the same issues are present (specific known sequences in mouse and human, wherein the terms encompass unknown variants/mutants/species and wherein the identity of the unknown variants/mutants/species is unpredictable). Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the amino acid itself or isolated protein is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification(i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have

previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA." See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

10. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The instant claim recites an antibody which binds the same epitope as the antibody recited in the claim. However, the specification does not disclose the identity of the epitope bound by the antibody recited in the claim (for example at the amino acid level). The identity of said epitope is unpredictable in the absence of experimental evidence disclosing the nature of said epitope. Therefore, the skilled artisan cannot envision the detailed structure of the encompassed epitope and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the amino acid sequence encoding the epitope is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the

University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification(i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA." See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

11. Regarding the application of prior art, the 7B6.15.11 hybridoma/antibody is not disclosed in parent application 60/398530. Regarding the application of prior art, the antibody of claim 23 is not disclosed in parent application 60/398530. Regarding claim 1, the “agonist antibody” as per defined in the instant application encompasses antibodies with the properties of claim 23, whilst parent application 60/398530 does not

include such antibodies in the definition of "agonist antibody". In addition, for the same reasons that the claimed inventions lack written description as per above, said claims are not entitled to priority to parent application 60/398530.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-5,14,23,25,28,31,37,55 are rejected under 35 U.S.C. 102(a) as being anticipated by Seshasayee et al.
Seshasayee et al. disclose the 7B6.15.11 (aka 7B6) murine monoclonal antibody (see page 283, first column and Figure 5) wherein said antibody inherently has the properties recited in the claims because said antibody is the claimed antibody. Seshasayee et al. disclose that they generated the aforementioned murine antibody wherein said antibody would be made by the claimed hybridoma (see page 283, first column).

14. Claims 1,3,23,37,38,53-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashkenazi et al. (WO 01/60397) as evidenced by Seshasayee et al..
Ashkenazi et al. disclose humanized anti TACI agonist antibodies which activate the TACI receptor wherein the TACI receptor comprises the sequence recited in claim 55 (see page 9, first paragraph and fourth paragraph, page 41, last paragraph, page 63). Said antibodies inherently have the functional property of claim 1 because said activation of said receptor causes the functional activity recited in claim 1 (see Seshasayee et al., page 283, first column). The antibodies can be made recombinantly in prokaryotic (unglycosylated) or eukaryotic (glycosylated) hosts (see pages 48-51).

The antibodies can include antibody fragments (see page 62, second paragraph). The agonist antibody can enhance the activity of a native ligand for TACI (see page 9), wherein the native ligand is TALL-1 (aka BLyS) (see page 8) and wherein said antibody would therefore not inhibit binding of TALL-1 to the TACI receptor.

15. Claim 1-3,5,14,23,31,37,38,51,53-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Kindsvogel (US 2007/0049735) as evidenced by Seshasayee et al.

Kindsvogel teaches humanized and murine monoclonal agonist antibodies which bind TACI without binding BCMA (see [0028], [0014], [0015], [0223], [0224]). Said antibodies inherently have the functional property of claim 1 because said activation of said receptor causes the functional activity recited in claim 1 (see Seshasayee et al., page 283, first column). Said antibodies can be antibody fragments or antibodies conjugated to a cytotoxic agent (see [0016]). Said antibodies can bind the peptide recited in claim 55 (see [0110] and SEQ. ID. 4). The anti-TACI antibody of Table 1 ([0224]) has the same functional activity as the 7B6.15.11 antibody, which suggests that it recognizes the same epitope wherein said antibody would therefore also have the same functional attributes. Said antibody comprises "a sequence" from the antibody of claim 31 wherein "a sequence" encompasses a two amino acid sequence (the art recognizes that most antibodies have regions of amino acid similarity, especially in the framework regions and other nonbinding regions of the variable domain). The antibodies can be made recombinantly in prokaryotic (unglycosylated) or eukaryotic (glycosylated) hosts (see [0109]-[0122]).

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron, Ph.D./
Primary Examiner, Art Unit 1644